



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/018,026

06/11/2002

Atle Bjornerud

NIDN-10403

4684

36335

7590

01/26/2011

GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

SMITH, RUTH S

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

01/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/018,026
Filing Date: June 11, 2002
Appellant(s): BJORNERUD ET AL.

Craig M. Bohlken
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 18,2010 and October 18,2010
appealing from the Office action mailed February 17,2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying
by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal 2006-2266

The Examiner notes that the decision of the Examiner in the prior appeal was affirmed with the exception of claim 30 which recited generating image values indicative of renal perfusion. The Board noted that while the references cited by the Examiner taught generating images indicative of renal artery stenosis grade, none of the references cited suggested generating images values indicative of renal perfusion. The Examiner has now provided teachings which show a relationship between perfusion and stenosis grade.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 24-29,32,33.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,381,486	MISTRETTA et al	4-2002
5,128,121	BERG et al	7-1992
6,411,837	FISCHER	6-2002
2004/0208827	McMURRY et al	10-2004

Stark et al, "Magnetic Resonance Imaging" Mosby-Year Book, Volume One, 1992, pp 327-328

Schurfeld et al "Renovascular hypertension-a factor of progression?", 1997, Vol. 26, No. 6, Abstract

Lerman et al, "Noninvasive Evaluation of a Novel Swine Model of renal Artery Stenosis", Journal American Society of Nephrology, 1999, pp 1455-1465

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 26,27 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 26, 27, "the method of said blood pool MR contrast agent" lacks antecedent basis.

Claim 24 has been rejected under 35 U.S.C. 102(e) as being anticipated by Mistretta et al (6,381,486). Mistretta et al disclose a method of MRA which includes administering by injection a bolus of a blood pool MR contrast agent, generating a contrast enhanced MR image of a body part during the first pass of the contrast agent, generating at least one further MR image of the body part in a "steady state" portion of the exam when the contrast agent has become substantially uniform. Mistretta et al disclose that it is known to image the kidney in examining the vasculature. It should be noted that the claim only sets forth a step of administering a contrast agent and generating two images. The recitation of "thereby allowing both visualization and gradation of renal artery stenosis and quantification of renal perfusion" is not considered to be a limiting step in the method but merely a possible use of the method steps. The method of Mistretta et al would be capable of "allowing" visualization of the above noted parameters if so desired.

In the alternative, if one were to interpret the recitation of "thereby allowing both visualization and gradation of renal artery stenosis and quantification of renal perfusion" as limiting, claims 24,32-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ("Magnetic Resonance Imaging")

Art Unit: 3737

and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al. Mistretta et al disclose a method of MRA which includes administering by injection a bolus of a blood pool MR contrast agent, generating a contrast enhanced MR image of a body part during the first pass of the contrast agent, generating at least one further MR image of the body part in a "steady state" portion of the exam when the contrast agent has become substantially uniform. Mistretta et al disclose that it is known to image the kidney in examining the vasculature. Stark et al disclose using MRA to examine the kidney to determine the presence of abnormalities such as renal stenosis. The MR data obtained by Stark et al is indicative of renal stenosis. Schurfeld et al disclose that "a higher grade renal artery stenosis causes a reduced arterial perfusion..." Lerman et al disclose on page 1462 that perfusion correlates significantly with severity of stenosis. Therefore, the MR data obtained by Stark et al which is "indicative" of renal stenosis grade is inherently also "indicative" of renal perfusion. It would have been obvious to one skilled in the art to have modified Mistretta et al such that the method is used to examine the kidney and to determine the presence or absence of any conditions which can cause known abnormalities such as renal artery stenosis grade, renal perfusion, intra-parenchymal blood volume and parenchymal damage. The modification merely involves using the known method of examining vasculature, as disclosed by Mistretta et al, on the kidney to provide a diagnosis of such an organ as taught by Stark et al. The modified method would allow one to quantify both renal stenosis and renal perfusion if so desired.

Art Unit: 3737

Claims 25-27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ("Magnetic Resonance Imaging") and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of Berg et al. Berg et al disclose MRI where a blood pool contrast agent comprising a superparamagnetic contrast agent is used. The contrast agent can include the particles as set forth in claims 26,27. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that the contrast agent is the one disclosed by Berg et al. Such a modification merely involves the substitution of one known type of blood pool contrast agent for another.

Claim 28 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ("Magnetic Resonance Imaging") and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of Fischer. Fischer discloses the use of a T_2^* - weighted image during a first pass of an MR contrast agent. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that during the first pass of the contrast agent a T_2^* - weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during the first pass of a contrast agent for another.

Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ("Magnetic Resonance Imaging") and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of McMurray et al. McMurray et al disclose the use of a T₁- weighted image in combination with an MR contrast agent. The advantage of using a T₁- weighted image is well known in the art. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that during the steady-state portion of the examination a T₁- weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during a steady state portion of an MR contrast enhanced method for another.

(10) Response to Argument

It is respectfully submitted that claim 24 does **not** set forth a method which includes providing quantified data for both renal perfusion and renal stenosis grade in a single examination. The claim steps merely allow visualization and gradation of renal artery stenosis and quantification of renal perfusion. This does not provide a method which positively includes providing quantified data for both renal perfusion and renal stenosis grade in a single examination. This is analogous to a method comprising the step of filling an automobile with gasoline **thereby allowing the automobile to be driven**. Such a method fails to positively set forth a step of actually driving the automobile and merely sets forth a method of filling it with gasoline.

The Appellant argues that the method provides for quantification of both the morphological degree of renal artery stenosis and the renal parenchymal perfusion in a single examination. It is respectfully submitted that the claim language does not require the quantification of such data and the method does not require that all data be provided in a *single* examination.

The Examiner does not agree with Appellant's remarks that none of the prior art documents are related to renal perfusion. Both Schurfeld et al ("Renovascular hypertension-a factor of progression?") and Lerman et al are cited as a teaching that renal stenosis is inherently indicative of renal perfusion. It should be further noted that the modified method of Mistretta would allow one to quantify both renal stenosis and renal perfusion if so desired.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ATLE BJORNERUD, KAREN BRILEY-SAEBO, MICHAEL V. KNOPP,
STEPHEN MCGILL, and STEFAN O. SCHOENBERG

Appeal 2006-2266 Application 10/018,026 Technology Center 3700

Decided: May 22, 2007

Before TERRY J. OWENS, MURRIEL E. CRAWFORD, and ANTON W.
FETTING, Administrative Patent Judges.

CRAWFORD, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

This appeal involves claims 24 to 33, the only claims pending in this application.
We have jurisdiction over the appeal pursuant to 35 U.S.C. 6(b).

The claims are directed to method of magnetic resonance ("MR") imaging of a kidney in vascularized human or non human body. Claim 24 is illustrative:

24. A method of magnetic resonance imaging of a kidney in vascularized human or non human body comprising the steps of:

administering into the vasculature of said body a bolus of a blood pool MR contrast agent;

generating a contrast enhanced MR image of said kidney during the first pass of said contrast agent;

generating at least one further MR image of said kidney after the concentration of said contrast agent throughout the blood of said body has become substantially uniform and, deriving from said MR images values indicative of one of renal perfusion and renal artery stenosis grade.

The Examiner relies on the following prior art references to show unpatentability:

Berg US 5,128,121 Jul. 7, 1992

Mistretta US 6,381,486 B1 Apr. 30, 2002

Art Unit: 3737

Fischer US 6,411,837 B1 Jun. 25, 2002

McMurry US 2004/0208827 A1 Oct. 21, 2004

Stark, "Magnetic Resonance Imaging," Mosby-Year Book, Vol. 1, pp. 327-328(1992)

The rejections as presented by the Examiner are as follows:

1. Claims 24, 30 to 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mistretta in view of Stark.
2. Claims 25 to 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mistretta in view of Stark and further in view of Berg.
3. Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Mistretta in view of Stark and further in view of Fischer.
4. Claim 29 is rejected under 35 U.S.C. § 103(a) as unpatentable over Mistretta in view of Stark and further in view of McMurray.

Appellants contend that neither Mistretta nor Stark discloses a method of acquiring renal perfusion information of the kidney. Appellants further contend that there is no motivation to combine the teachings of Mistretta and Stark.

ISSUES

The first issue is whether the Appellants have shown that the Examiner erred in finding that the invention would have been obvious in view of the combined teachings of Mistretta and Stark. This issue turns on whether the claims require a method of magnetic imaging of the kidney that includes a step of generating a MR image of the kidney indicative of renal perfusion.

The second issue is whether the Appellants have shown that the Examiner erred in finding that there was a reason to combine the teachings of the applied references.

FINDINGS OF FACT

Appellant's claim 24 recites that the step of generating at least one further MR image of the kidney includes the step of deriving from the MR image values indicative of one of renal perfusion and renal artery stenosis grade. Therefore, claim 24 requires that the MR image values obtained be indicative of renal per fusion or renal stenosis grade.

Claim 30 recites that the values are indicative of renal perfusion.

Mistretta discloses that diagnosis studies of human vasculature have many applications and that X rays have been used to image the vasculature of the kidney. However, the use of X rays has certain drawbacks such as subjecting the patient to potentially ionizing radiation and often requiring the use of an invasive catheter (col. 1, 11. 14 to 25). Mistretta further discloses that Magnetic Resonance Imaging (MRI) can be used to obtain images of human vasculature with advantageous results (col. 1, 11.41 to col. 3, 1.20).

Stark discloses MRI can be used to diagnosis the renal stenosis grade (page 3).

Berg discloses that in MRI, the contrast in the image generated may be enhanced by introducing into the zone being imaged an agent, referred to as a contrast agent (col. 1, 11. 10 to 12). The enhanced contrast obtained with the use of the contrast agent enables particular organs or tissues to be visualized more clearly by increasing or by decreasing the signal level of the particular organ or tissue relative to that of its surroundings (col. 1, 11. 17 to 21). Berg

Art Unit: 3737

discloses that some materials used as contrast agent achieve this effect because they are superparamagnetic (col. 1, 11.6 to 30).

Fischer discloses the use of T_2 weighted contrast agents in MRI (col. 6, 1.9 to col. 7, 1. 13). Appellants have not argued that Fischer does not disclose the use of T_2 weighted contrast agents.

McMurray discloses the use of T_1 weighted contrast agents in MRI (paragraph 0040). Appellants have not argued that McMurray does not disclose the use of T_1 weighted contrast agents.

PRINCIPLES OF LAW

In establishing a case of obviousness based on a combination of prior art references, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the teachings of the prior art references. *KSR Int'l v. Teleflex Inc.*, 127 S.Ct.1727, 82 USPQ2d 1385 (2007).

ANALYSIS

Claim 24 does not require that the MRI method include generating image values indicative of renal perfusion. The disclosure in Stark that MRI may be used to generate images indicative of renal artery stenosis grade is sufficient to meet the limitations of the claims.

Claim 30, however, does recite generating image values indicative of renal perfusion. Neither Mistretta nor Stark discloses or suggests generating image values indicative of renal perfusion.

There is a reason to combine the teachings of Mistretta and Stark.

Mistretta discloses that there are problems with the use of X-rays to image vasculature of the kidney and that MR/can be used to image human vasculature. Stark discloses that MRI can be used to diagnose kidney stenosis grade. A person of ordinary skill in the art would have been motivated by the teaching in Stark that MRI may be used to diagnose kidney grade to use the MRI technique disclosed in Mistretta to diagnose kidney stenosis grade.

There is reason to combine the teachings of Mistretta and Stark with , the teachings of Berg. A person of ordinary skill in the art would have been motivated by the teaching of Berg to use a contrast agent that contains superparamagnetic species in the MRI method disclosed in Mistretta to obtain the advantages taught by Berg i.e. to enable the particular organ or tissue to be visualized more clearly. There is reason to combine the teachings of Mistretta and Stark with either Fischer or McMurray because each reference is evidence that the use of T_1 or T_2 weighted image was known in the art. A person or ordinary skill in the art would have been motivated to substitute one type of known weighted image for another type of known weighted image.

CONCLUSION/ORDER

The examiner's rejection of claims 24 to 29 and 31 to 33 is sustained. The examiner's rejection of claim 30 is not sustained.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ruth S. Smith/

Primary Examiner, Art Unit 3737

Conferees:

Robert Chen

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777

/Michael Phillips/ RQAS